

REMARKS

Claims 32-54 are pending, with claims 32 and 41 being the independent claims. By this Amendment, claims 32 and 41 have been amended.

The Examiner rejects claims 32-54 under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,682,519 to Schon ("Schon"). Applicants respectfully traverse this rejection in view of the following remarks:

The Examiner relies upon Schon to anticipate teach or suggest each an every feature defined by claims 32 and 41. This rejection position is incorrect for at least the following reasons.

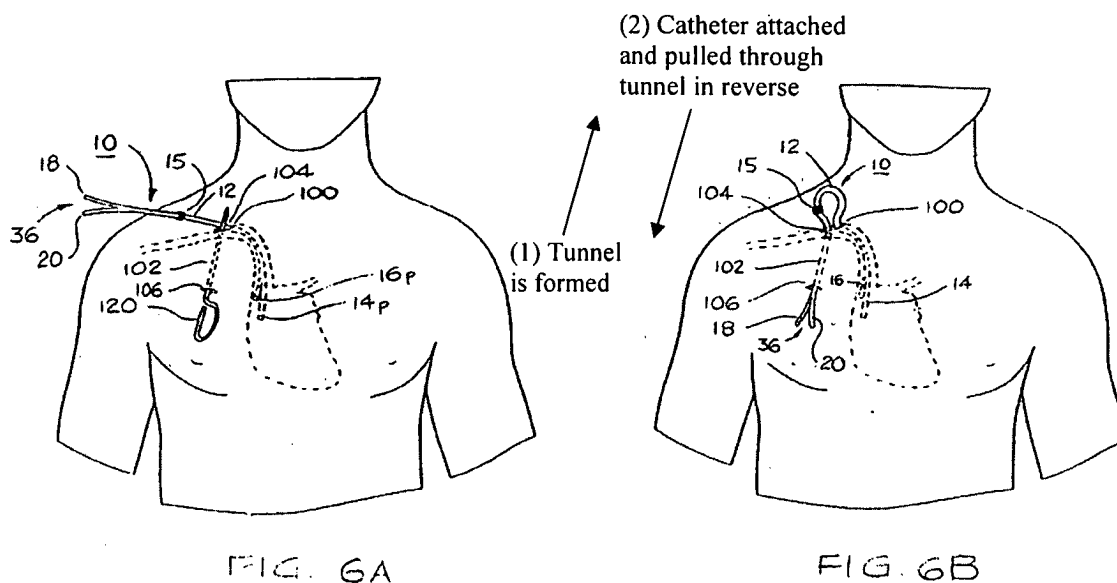
Independent claims 32 and 41, as amended, recite a method for surgically implanting a multi-lumen catheter having "a one-piece multi-lumen portion having a plurality of integrally formed lumens." At least this feature, in combination with the other features recited in independent claims 32 and 41, is not taught or suggested by Schon.

The Present Application discloses a catheter 10 including multi-lumen portion 12 having two or more lumens 5 and 6 formed within a single one-piece catheter tube. The distal ends of each lumen 5 and 6 of the multi-lumen tube portion 12 are connected to distal extension tubes 18 and 20, respectively, forming a Y-shaped distal end 30 of the catheter 10. Schon, on the other hand, discloses a multi-lumen catheter assembly 10 made from two separate catheters 16, 18. A portion of the catheters 16, 18 are bound together by a retaining sleeve 14, but the remainder of the catheters 16, 18 are unattached along their entire length. Thus, Schon does not teach or suggest catheter including "a one-piece multi-lumen portion having a plurality of integrally formed lumens."

Further, the insertion method in independent claims 32 and 41 includes a step in which "after the subcutaneous tunnel is formed, guiding ... at least a portion of the multi-lumen tube portion through the subcutaneous tunnel." At least this feature, in combination with the other features recited in independent claims 32 and 41, is not taught or suggested by Schon.

As shown in FIG. 6A-B of the Present Application (reproduced below), the insertion method includes inserting the proximal tips 14p, 16p of the catheter 10 into the desired location within the patient using a standard technique, such as the Seldinger technique, and then reverse

tunneling the distal end 36 of the catheter 10 through one subcutaneous tunnel 102. For example, after the tips of the catheter 10 are placed in the patient's body, a subcutaneous tunnel 102 is formed by a trocar beginning at a remote location and moving towards the location of the incision from which the catheter extends. After the trocar has created the subcutaneous tunnel 102, the distal end 36 of the catheter 10 is attached to the trocar and pulled back through the tunnel 102 away from incision.



In contrast, the insertion method in Schon discloses inserting the tips of catheters into a vein 32, such as using a standard Seldinger technique, and then forward tunneling the two catheters in separate subcutaneous tunnels. For example, after the tips of each of the two catheters are placed in the patient's body, the end of the first catheter 16 extending from the patient's body is attached to a tunneling device. The tunneling device, with the catheter attached, is then forced forward through a subcutaneous tissue of the patient, forming a tunnel 56 is formed using a tunneling device which attaches to the proximal end 59 of the first proximal portion 48 of the first catheter 16 and while pulling the catheter 16 through the tunnel. The disclosure of Schon with respect to tunneling of the catheters subcutaneously is essentially limited to col. 11, lines 2-15. Thus, to the extent that Schon makes any particular disclosure as to tunneling of catheters, it discloses only forward tunneling. That is, the catheter is attached to the trocar before any tunnel exists and the trocar simultaneously excavates a subcutaneous tunnel while threading the catheter through the tunnel.

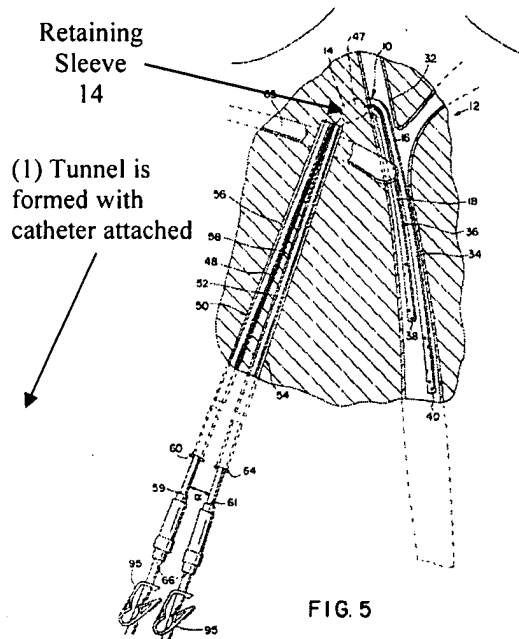


FIG. 5

Additionally, during the tunneling process in the Present Application, the Y-shaped distal end 36 of the catheter 10 is passed through the tunnel 102 such that the distal extension tubes 18 and 20 and a portion of the multi-lumen portion 12 extends through the first end 104 of the tunnel and out through the second end 106 of the tunnel. Consequently, at least a portion of multi-lumen portion 12 must be guided through the tunnel 102.

However, Schon teaches that the retaining sleeve 14 is used to subcutaneously anchor the catheter assembly by maintaining the position of the retaining sleeve below the incision site and outside the area to be catheterized (See col. 2, lines 50-55). Schon also discloses that it is important that the retaining sleeve 14 be made sufficiently wide to prevent the retaining sleeve 14 from passing into the vein 32 or other area to be catheterized 12, such that the retaining sleeve 14 remains outside the area to be catheterized 12 after insertion. (See col. 9, lines 40-57). Thus, contrary to the Examiner's assertion, the retaining sleeve 14 must remain between the area to be catheterized 12 and the subcutaneous tunnels 56 and 58 in order to anchor the catheter. This specifically teaches away from "guiding ... at least a portion of the multi-lumen tube portion through the subcutaneous tunnel" as required by claims 32 and 41.

Accordingly, Applicants respectfully submit that Schon does not teach or suggest each an every feature of independent claims 32 and 41.

For at least the reasons set forth above, Applicants submit that independent claims 32 and 41 are patentable, and kindly request that that the rejection be withdrawn.

CONCLUSION

In view of the preceding amendments and remarks, reconsideration and withdrawal of the various objections and rejections set forth in the Office Action is respectfully requested.

The Director is hereby authorized to charge \$940, which covers the \$130 fee for a one (1) month extension of time and the \$810 fee for a Request for Continued Examination (RCE), to Deposit Account Number 01-1785.

Authorization is also given to charge any outstanding amount or credit any overpayment, to Deposit Account No. 01-1785.

Respectfully submitted,

AMSTER, ROTHSTEIN & EBENSTEIN LLP
Attorneys for Applicants
90 Park Avenue
New York, NY 10016
(212) 336-8000

Dated: New York, New York
May 27, 2009

By: /Brett M. Pinkus/
Brett M. Pinkus
Registration No. 59,980